UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/852,666	05/07/1997	KIRIN K. CHADA	UMD-1.0-037C	7255

22249 7590 05/20/2002

LYON & LYON LLP
633 WEST FIFTH STREET
SUITE 4700
LOS ANGELES, CA 90071

EXAMINER	
KAM, CHIH MIN	
ART UNIT	PAPER NUMBER
1653	35

DATE MAILED: 05/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/852,666	CHADA ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *50 and 53-59* is/are allowed.

6)☒ Claim(s) *47-49, 51 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Prosecution Application

1. The request (Paper No. 33) filed on March 6, 2002 for a Continued Prosecution Application (CPA) under 37 C.F. R. 1.53 (d) based on parent application No. 08/852,666 is acceptable and CPA has been established. An action on the CPA follows.

Status of the Claims

2. Claims 47-59 are pending.

Applicants' amendment filed on March 6, 2002 (Paper No. 34) is acknowledged. Applicants' response has been fully considered. New claims 50-59 have been added.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 47-49, 51 and 52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for screening candidate compounds capable of inhibiting HMGI biological activity comprising the first step of immobilizing an HMGI protein or a functional fragment on a solid surface, or comprising the steps of transfecting into a cell a DNA construct and administering to the cell a candidate compound, wherein the compound is identified by binding assay screening techniques that include HMGI protein or a functional fragment, does not reasonably provide enablement for a method for screening candidate compounds capable of inhibiting HMGI biological activity comprising the step of immobilizing any HMGI fragment on a solid surface, or comprising the steps of transfecting into a cell a DNA

construct and administering to the cell a candidate compound, wherein the compound is identified by binding assay screening techniques that include any HMGI fragment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 47-49, 51 and 52 are directed to a method for screening candidate compounds capable of inhibiting HMGI biological activity comprising the first step of immobilizing an HMGI protein or a fragment on a solid surface (claims 47-49), or comprising the steps of transfecting into a cell a DNA construct and administering to the cell a candidate compound, wherein the compound is identified by binding assay screening techniques that include HMGI protein or a fragment (claim 51 and 52). The specification, however, only discloses cursory conclusions without data supporting the findings, which states that a method for screening candidate compounds capable of inhibiting HMGI biological activity comprising the first step of immobilizing an HMGI protein or a fragment on a solid surface, or comprising the steps of transfecting into a cell a DNA construct and administering to the cell a candidate compound, wherein the compound is identified by binding assay screening techniques that include HMGI protein or a fragment (page 11, lines 26-36). There are no indicia that the present application enables the full scope in view of a method for screening candidate compounds capable of inhibiting HMGI biological activity by immobilizing an HMGI protein or a fragment on a solid surface as discussed in the stated rejection. The present application provides no indicia and no teaching/guidance as to how the full scope of the claims is enabled. The factors considered in determining whether undue experimentation is required, are summarized in In re Wands (858

F2d at 731,737, 8 USPQ2d at 1400,1404 (Fed. Cir.1988)). The factors most relevant to this rejection are the breath of the claims, the absence of working examples, the state of the prior art and relative skill of those in the art, the unpredictability of the art, the nature of the art, the amount of direction or guidance presented, and the amount of experimentation necessary.

(1). The breath of the claims:

The breath of the claims is broad and encompasses an unspecified variants regarding HMGI fragments, which are not adequately described or demonstrated in the specification.

(2). The absence of working examples:

There are no working examples indicating the claimed variants and the methods in association with the variants except for HMGI protein or a functional fragment.

(3). The state of the prior art and relative skill of those in the art:

The general knowledge and level of the skill in the art do not supplement the omitted description, the specification needs to provide specific guidance on the identities of fragments which are involved in the protein-protein interaction but not a functional fragment to be considered enabling for variants.

(4). Predictability or unpredictability of the art:

The claims encompass a method for screening candidate compounds capable of inhibiting HMGI biological activity by immobilizing an HMGI protein or a fragment on a solid surface, or, by transfecting into a cell a DNA construct and administering to the cell a candidate compound, wherein the compound is identified by binding assay screening techniques that include HMGI protein or a fragment. However, the specification does not identify various fragments which are

involved in the protein-protein interaction but not a functional fragment, the invention is highly unpredictable regarding the outcome of the screening method.

(5). The amount of direction or guidance presented and the quantity of experimentation necessary:

The claims are directed to a method for screening candidate compounds capable of inhibiting HMGI biological activity by immobilizing an HMGI protein or a fragment on a solid surface, or, by transfecting into a cell a DNA construct and administering to the cell a candidate compound, wherein the compound is identified by binding assay screening techniques that include HMGI protein or a fragment. The specification only indicates HMGI is the architectural component of the enhanceosome, and disruption of the enhancesome assembly by interfering either with protein-DNA or protein-protein interactions of HMGI proteins results in loss of transcriptional regulation. Small molecules which possess a structure similar to the HMGI DNA-binding domain can inhibit HMGI biological funtion (page 53, lines 20-36). Furthermore, the specification indicates the amino acid sequence involved in the DNA-protein binding or the sequence implicated in the protein-protin binding of HMGI (page 54, lines 18-28). The specification has not identified any fragment other than the DNA-binding doamin or protein-binding domain would interfere with the DNA or protein binding of HMGI. There is no working examples indicating a compound that binds any region of HMGI (any fragment of HMGI) would disrupt protein-DNA or protein-protein interaction, thus results in loss of transcription regulation. Since the specification fails to provide sufficient guidance on the identification of the fragments which are not functional fragments but are involved in the protein-binding of HMGI,

it is necessary to carry out further experimentation to identify the fragments and assess their effects on the protein binding.

(6). Nature of the Invention

The scope of the claims encompass for screening candidate compounds capable of inhibiting HMGI biological activity by immobilizing an HMGI protein or a fragment on a solid surface, or, by transfecting into a cell a DNA construct and administering to the cell a candidate compound, wherein the compound is identified by binding assay screening techniques that include HMGI protein or a fragment, but the specification does not indicate the identity of the fragments which are not functional fragments but are involved in the protein-binding of HMGI. Thus, the disclosure is not enabling for the reasons discussed above.

In summary, the scope of the claim is broad, the working example does not demonstrate the claimed variants, the art is unpredictable regarding the claimed variants, and the guidance and the teaching in the specification are limited, therefore, it is necessary to have additional guidance and to carry out further experimentation to assess the effect of the fragments in the screening method.

In response, applicants indicate that the method is to use HMGI or its fragment in a binding assay to identify candidate compounds which may or may not inhibit the biological function of HMGI based on the compounds' ability to bind to HMGI or its fragment, and HMGI is the architectural component of the enhanceosome, it must interact with multiple proteins along with DNA, thus, theoretically, any compound that binds to HMGI, regardless of what region it binds to, could disrupt the interaction. Applicants further indicate the binding assay, which employs the immobilized protein or fragment as the first filter and is only one part for the

screening method. However, the argument is not persuasive because the specification has not demonstrate the compounds which bind to unspecified fragments without functional domains such as DNA-binding domain or protein-binding domain of HMGI could disrupt the interaction as indicated the section above. Applicants also indicate "theoretically" it could happen, but it is stated without supporting scientific data.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 47-49, 51 and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 47-49, 51 and 52 are indefinite because of the use of the term "a fragment thereof" or "fragments thereof". The term "a fragment thereof" or "fragments thereof" renders the claim indefinite, it is not clear which fragment of HMGI is, e.g., whether this fragment has the same biological function as HMGI, whether the fragment contains a DNA binding domain or a protein-protein interaction domain?

Claim 47 is also indefinite as to the term "HMGI", it is not clear what "HMGI" means. Claim 52 is also indefinite as to the terms "HPLC" and "SPR", it is not what "HPLC" or "SPR" means. A full spelled out word for the term should be indicated in the first occurrence.

In response, applicants indicate that the method is to use HMGI or its fragment in a binding assay to identify candidate compounds which may or may not inhibit the biological function of HMGI based on the compounds' ability to bind to HMGI or its fragment, and any

compound that binds to HMGI, regardless of what region it binds to, could disrupt the interaction. The argument is not persuasive because the specification has not identified these fragments as indicated in the section of rejection under 35 U.S.C. 112, first paragraph.

Conclusion

6. Claims 47-49, 51 and 52 are rejected. It appears claims 50 and 53-59 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

Karen Cochrane Carlson PhD
KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

***
May 9, 2001